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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,858	03/14/2002	Bonnie M. Davis	U 013913-4	4479

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EXAMINER
CLAYTOR, DEIRDRE RENEE

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
11/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nyuspatactions@ladas.com

Office Action Summary	Application No.	Applicant(s)	
	10/099,858	DAVIS, BONNIE M.	
	Examiner	Art Unit	
	Renee Claytor	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-36 and 38* is/are pending in the application.

4a) Of the above claim(s) *5-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-4 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicants argue over the 35 USC 112 rejection concerning new matter that no one reading the present disclosure would conclude that the applicant contemplated the invention as being treatment of patients with Alzheimer's disease but that the invention clearly relates to other cognitive dysfunction.

As discussed in prior responses, it is noted that there is no teaching in the specification that the treatment is not intended for those who are being treated for Alzheimer's disease. The field of the invention, as described in the first paragraph of the specification, relates to the use of nicotinic receptor modulators for treatment of cognitive and other central nervous system dysfunction resulting from low LDL-cholesterol values. There is no mention in the specification, nor any information in the specification, that leads one to believe that the patient does not have Alzheimer's disease. The only mention of Alzheimer's disease is in the background section. Further, the specification teaches that the treatment of cognitive dysfunction is to be accomplished by modulating nicotinic receptors. Regardless of how cognitive dysfunction occurs, treatment of cognitive dysfunction can be accomplished with nicotinic receptor modulation. Further, there is nothing to indicate that the patient population indicated in the specification that cognitive dysfunction results from Alzheimer's disease. Therefore the new matter rejection is deemed proper and is maintained herein.

Applicant's amendments to the claims are sufficient to overcome the 35 USC 112, first paragraph scope of enablement rejection and the rejection is hereby withdrawn.

Applicant's arguments over the 35 USC 103 rejection are that the logical conclusion from the prior art references is that one will not need to take drugs whose primary current use is to treat Alzheimer's disease. This is not persuasive because if there are cognitive defects, regardless of the etiology, galanthamine is a known drug on the market for treating Alzheimer's disease which is associated with cognitive dysfunctions. Accordingly, the rejection is maintained and given below.

Claim Objections

Claim 1 objected to because of the following informalities: there is a period in line 14 after "unsubstituted benzoyloxy group". There should be a comma instead of a period. Appropriate correction is required.

Claim Rejections – 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-4, and 37-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Amendment to the claims in which it is stated "…other than one being treated for Alzheimer's disease with a nicotinic allosteric potentiator…." is not supported in the specification and is considered new matter.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-4 and 38 rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (U.S. Patent #4,663,318) in view of Kivipelto (BMJ (2001) 322: 1447-1451) and Simons et al. (Neurology (2001) 57: 1089-1093).

Davis et al. teach that galanthamine is useful for the treatment of Alzheimer's disease (see whole document).

Davis et al. do not specifically teach that the patient population receiving the treatment is associated with low LDL-cholesterol values or that the low cholesterol values are a result of treatment with HMG-CoA reductase inhibitors.

Kivipelto et al. teaches that high serum cholesterol increases the risk of Alzheimer's disease (pg. 1449, first paragraph and Table 2).

Simons et al. teach that there is a decreased prevalence of Alzheimer's disease associated with the use of statins (pg. 1091, paragraph 2). It is taught that statins cross the blood-brain barrier and decrease de novo cholesterol synthesis by inhibiting HMG-CoA reductase (pg. 1091, paragraph 2).

It would be obvious to one having ordinary skill in the art at the time of the invention to add to the drug regimen of an elderly patient that suffers from a cognitive disorder and is taking statins for hypercholesteremia, an effective amount of galanthamine to improve cognitive behavior because Davis teaches that galanthamine is effective in treating Alzheimer's disease, which is a disease of cognitive impairment. One would have been motivated to do so because the prior art teaches that high levels of cholesterol and Alzheimer's disease are related (as taught by Kivipelto), and that patients receiving statins for hypercholesteremia have a lower incidence of Alzheimer's disease (as taught by Simons); therefore, one would have a reasonable expectation of success with treatment of galanthamine for a cognitive disorder.

Furthermore, Applicant has not provided any evidence showing the criticality of cholesterol levels at 109 mg/dl. Accordingly, identifying suitable patients by observing their cholesterol levels during hypercholesteremia treatment would be achieved by routine experimentation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627